Dragon, Karen E.

From: Cristine Fargo [cfargo@safetyequipment.org]
Sent: Thursday, August 25, 2005 1:30 PM
To: NIOSH Docket Office
Subject: Comments to docket NIOSH DOCKET-52

Attached please find comments to the docket from the International Safety Equipment Association on the draft guidance document for CBRN Air Purifying Respirators.

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INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

Via Email: niocindocket@cdc.gov

August 25, 2005

NIOSH Docket Office
Reference: NIOSH DOCKET -052
Robert A. Taft Laboratories, M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Re: NIOSH Interim Guidance on the Use of Chemical, Biological, Radiological and Nuclear (CBRN) Full Facepiece, Air-Purifying Respirators/Gas Masks Certified under 42 CFR Part 84 CBRN APR User Guide (draft dated July 8, 2005)

Dear Sir/Madam:

ISEA supports NIOSH in its efforts to develop guidelines for emergency responders using NIOSH-approved CBRN APR devices. ISEA member manufacturers of respiratory protection have reviewed the draft guidelines (dated July 8, 2005) and offer the following comments.

General Summary

The responder community is demanding clarification concerning the use of CBRN APR devices. ISEA believes that this document does not provide sufficient information for users to make informed application decisions and in fact unreasonably restricts the use of these respirators.

The CBRN facepiece and canister system has been tested and certified against the most comprehensive NIOSH criteria developed for air purifying respirators, yet the canisters are not specifically approved for any substances. Traditional NIOSH equipment approvals provide information about the substances which the device is certified to protect against (e.g. 1000 ppm organic vapors, ammonia, chlorine, etc). That is not the case with the CBRN approval. While respirator systems are tested against a wide range of TICs and TIMs, they carry no specific approval.

The document appears to limit the use of this class of devices to "CBRN Environments only" but does not clarify what CBRN is and what those events entail. CBRN environments are not limited to terrorism. Without additional clarification the interpretation of users is likely to be that a "CBRN event" is the result of terrorist activity only.

CBRN applies to all NBC materials. Therefore equipment that has a CBRN approval is also appropriate for CBRN environments not associated with a WMD event. There are numerous chemical events to which responders might be called which would require APRs. There are some routine events for which law enforcement needs respiratory protection (hazmat, meth labs, riot control). The nature of the approval makes it unclear whether CBRN devices should be used.

Paragraph 3a indicates the proposed use criteria for CRN APR devices. It mandates 8 criteria which must be met in order to use CBRN APRs or in fact any air purifying respirators.

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ISEA recommends that NIOSH clarify the range of performance of the APRs, enhance the described applications for the use of the product to include applications beyond CBRN, and better identify what is included in the description CBRN.

Specific Section Edits

[Note: Text recommended for inclusion is underscored; text recommended for deletion is noted by ~~strikethrough~~.]

Page 9, 4th paragraph
Comment: Manufacturers disagree that the olive green color identifies the NIOSH CBRN canister. Olive green is the label color for mercury vapor, multi gas, hydrogen fluoride, formaldehyde, ethylene oxide and vinyl chloride. The letters CBRN will be more useful than color in identifying an appropriate canister, more so than the color.
Revise to read: "A NIOSH-approved CBRN APR ~~can be identified by its~~ has an olive green NIOSH canister label affixed…"

Page 9, paragraph 4.
Revise to read: "This is important because inadvertent mixing of similar parts on a respirator ~~could~~ will void the NIOSH approval…"

Page 9, First line in section 2.
Comment: The statement should be rewritten because whether a CBRN agent is "respiratory" depends on if it is airborne or not.
Revise to read: ~~Respiratory~~ CBRN agents are chemical, biological, radiological, and nuclear ~~inhalation~~ hazards which have the potential to be released and become airborne, creating an inhalation hazard during acts of terrorism.

Page 11, First paragraph in section 2b.
Comment: "Toxin" is a word that applies to many chemicals. In the sense that it is used here, the definition should indicate that it means toxins produce by microorganisms.
Revise to read: Biological agents consist of micro-organisms such as pathogens (which include disease causing bacteria, rickettsiae, and viruses) and toxins produced by microorganisms.

Page 11, sections 2b and 2c
Comment: These sections incorrectly indicate that the filter is effective only for biological, radiological and nuclear agents. Since the filter is a P-100 particulate filter it is effective against many other aerosols including that from building collapse etc.

Page 13, First paragraph, bullet 4, footnote 2.
Comment: The footnote indicates that the NIOSH IDLH values should be used; however, these values may contradict those used by OSHA for enforcement. In many cases the NIOSH method used to revise the IDLHs resulted in IDLHs equal to or less than OSHA PELs.

For example, the 2004 IDLH for tetrachloroethylene is 150 ppm. The OSHA PELs for tetrachloroethylene include a TWA, a ceiling limit that allows for 5 minutes of exposure above 200 ppm and below 300 ppm in any 3 hour period and a maximum peak of 300 ppm. To comply with OSHA, one does not need a respirator until the concentration reaches 200 or 300 ppm if they are in compliance with the TWA for tetrachloroethylene, yet NIOSH "requires" an SCBA. If 150 ppm is IDLH, many fatalities would have occurred.

ISEA recommends that NIOSH support the 2004 OSHA PELs. Since the OSHA values will be used to enforce the use of controls in the workplace, they should be the values referred to.

Page 13, footnote 3.2
Comment: ISEA members are not aware of any MUCs that a manufacturer has placed on the canisters. If there are not any in existence, NIOSH should delete this comment to prevent confusion.

Page 14, first sentence.
Comment: As written, this sentence indicates that the limitations listed here only apply to non-CBRN events, in which case the CBRN respirator cannot be used. Contrary to how the sentence is worded, we believe these limitations apply in all situations and are not unique to CBRN.
Revise to read: Cautions and limitations lettered as A, I, J, L, M, O, and S (located in Section 2 of these labels) apply ~~when non-CBRN~~ to all use situations. ~~conditions are present.~~

Page 14, Limitation I
Comment: ISEA members believe it is not appropriate to include this in the guidance documents, since it is not addressed in statement of standard. As a minimum, it should be indicated that this limitation would only appear when the respirator has electrical parts.

Page 15, Caution and Limitation R
Comment: ISEA believes that this statement does not provide any information that is specific to respirator use. This is information that needs to be provided under the hazard communication process and applies even when engineering controls are effective. In addition, this section provides some erroneous information. A CWA is not always more toxic than a TIC. There are several TICs that are worse than the CWAs. CWAs should be defined the first time it is used or refer the reader to the glossary. The entire section should be deleted and replaced with suggested revision as noted below.
Revise to read: "R" Some deadly exposures may take up to 24 hrs before an effect is noticed, e g., pulmonary edema caused by many chemicals.

Page 15, T
Comment: This paragraph will imply to some users that the respirator has a clock in it. A more thorough explanation is needed to explain the point.

Page 16 W
Comment: The explanation avoids the issue of canister interchangeability and should be mentioned. In the last sentence the use of the word "generated" is not appropriate.

Page 16, Y
Comment: The word "gradient" in the explanation is confusing and not needed. Non traditional terms that are used also add to the confusion in this paragraph.
Revise to read: Radioactive particulate hazards are protected against by the integral P-100 filtration media provided the concentration ~~gradient~~ does not exceed the protective capabilities of the respirator. Proper sealing techniques ~~of use must also be done~~ are necessary to ensure that the canister is not bypassed by contaminants as they enter into the breathing zone by compromised seal characteristics of the respirator facepiece-to-face sealing area. ~~to face interface region~~. Monitoring of radiation levels along with full radiation time, distance and shielding must be understood and implemented.

Page 16, Z explanation
Comment: As written, it appears that an important parameter was omitted: the specific test concentration.
Revise to read: CBRN APR canisters are required to provide protection for a minimum service life of 5 minutes when tested at the specified test concentrations, at a flow rate of 100 liters per minute, at 50+/-5% humidity and 25 +/- 5 deg C for each gas/vapor identified in the canister test challenge list. This means the canister is rated to provide you an extra level of protection to ~~ally~~ allow escape from unanticipated release, such as a detonated secondary device ~~respiratory hazard~~.

Page 17, HH
Comment: ISEA believes the statement should be rewritten for clarity. It should be revised as follows.
Revise to read: ~~"HH" When used at defined occupational exposure limits, the rated service time cannot be exceeded.~~ Follow established canister change schedules or observe End-of-Service-Life Indicators to ensure that canisters are replaced before breakthrough occurs.

Page 17, HH explanation
Comment: The explanation appears to confuse the canister service life with that of the CRUL by bringing in the 480 minutes.
Revise to read: Air-purifying respirators require specific canister change schedules. ~~deliberate use decision logic. CBRN CAP 1 is a rated service time for a CBRN canister. The entire CBRN APR, as a system has a 480 minute service life against GB and HD, a 15 minute test time against the TRA and a 5 minute high flow test time against the TRA. Do not exceed the use life of the canister because the canister is the component that has the shortest rated service time and therefore the default for use is to the canister.~~ Establish a canister change schedule. **Establish** ~~and~~ a respirator disposal schedule upon direct contact with CBRN agents, especially CWA. Use detection and monitoring operations to provide end of service life indicators that may contribute to canister replacement before breakthrough occurs.

Page 18, 3c
Comment: The first sentence is misleading as written and should be made clear, as it is one of the most popular questions received. Everything to this point indicates that NIOSH does not allow the CBRN approved respirator for industrial use. In fact, in the fifth paragraph of this section, it states, "CBRN canisters are to be used for CBRN response events only, not routine industrial use." The CBRN APR offers a solution to some employers where an air-purifying respirator wasn't available that is effective for their exposure. An example could be phosgene. It is possible to imagine an emergency response in which people are trapped, no CBRN agent is present, but cutting torches are being used to free the people and may generate silica dusts or metals fumes. These are clearly industrial applications, but if the CBRN APR cannot be used, the responders all have to go home and get an industrial respirator as silica dust and metal fume is clearly not a CBRN event.

Page 19, section 3d
Comment: If a canister is used during an escape, the canister must be replaced after use because the remaining service life is not known and an effective change schedule cannot be established.
Revise to read: After using the respirator to escape, the canister ~~should~~ must be replaced before reusing the respirator.

Page 19, 3e, second paragraph
Comment: Accepted terminology should be used.
Revise to read: The thread depth of the canister is ~~also a viable sealing surface~~ is important as it must ~~that~~ make up to the connector gasket and ~~provides a working~~ form a tight seal.

Page 19, 3e, third paragraph
Comment: As written, this paragraph gives permission to the incident commander to use different manufacturers' canisters but fails to point out that there are no standards that support it. Incident commanders needs to know that in this case they void the approval, and are assuming responsibility for that action.

Page 21, second paragraph
Comment: This paragraph incorrectly lists air-flow rate resistance as a factor affecting service life. Resistance is not a factor. At different resistances, the airflow will be different at the same work rate. If workers are not getting enough air, they raise their effort and thus airflow. Therefore airflow will meet the requirement.
Revise to read: "Actual service life of the CBRN canister is determined by the type of substance being removed, the concentration of the substance being removed, the ambient temperature at the time of removal, the specific ~~filtration element~~ canister being tested ~~(cartridge or canister)~~, the air-flow rate ~~resistance~~, and…"

Page 23, third paragraph
Comment: The statement should be rewritten for clarity.
Revised with comment: The 8-hour (vapor) and 2-hour (liquid) use life means eight continuous hours or two continuous hours in a single shift, day, or event. ~~The time intervals are continuous and cannot be divided; for example, the 8-hour period **cannot** be broken into four different 2-hour periods over the course of a day~~. Once permeation is started as a result of exposure to either liquid or vapor, permeation will continue even in the absence of additional liquid or vapor exposure to the respirator. Permeation will not stop once it has been exposed so the time period for the use life is a continuous time.

Page 23, section 7
Comment: Section 7 should be renamed "Methods for Determining a Canister Change Schedule." The text beginning with "The following recommendations…" in the third paragraph of 7a, and including the recommendations for CBRN APR use before, during and after an incident response, does not belong under this heading and should be separated into a new section.
Revise to read: 8. Use Recommendations for the CBRN APR
The following recommendations are applicable to defining best practice use guidelines relevant to the use of ~~a~~ the CBRN full face, tight fitting, nonpowered air-purifying respirator, also known as a gas mask:

Page 24 a.
Comment: This recommendation is not stated clearly and uses terms not understood by everyone.
Revise to read: Replace worn out items and ensure the APR ~~has~~ does not have a permanently ~~creased the faceblank~~ deformed facepiece while in storage.

Page 24 e
Comment: It is recommended that terms be used that are understandable to this audience, e.g., civilians.

Revise to read: e. Maintain a contingency ~~stockage~~ supply of unopened canisters, minimum two each per respirator, for real event use. Keep the caps on the canister until they are put on the respirator. Have systems in place that prevent inadvertent mixing of training and contingency canisters while in storage or in the workplace. Ensure all canister inlet and outlet caps are taken off prior to actual donning and use.

Page 25 first 12 lines
Comment: This paragraph is hard to understand and should be rewritten for clarity.
Revise to read: Actual use is dependent on the concentration ~~gradient~~ of exposure, weather conditions, and ~~time~~ duration of exposure…. With riot control agents, the integrated P-100 particulate filter of the CBRN APR… It is not recommended to just use a particulate N-series, R-series, or P-series industrial particulate filter for CS even if one of these filters is approved for use with a CBRN ~~APR~~ facepiece. For a CBRN response, use a CBRN rated canister on the CBRN ~~approved respirator~~ facepiece to make an approved respirator assembly.

Page 25, n
Comment: It would seem appropriate to mention the other factors that can interfere with optimum sealing such as temple bars on glasses. These spectacle kits will need to be obtained *before* an incident.

Page 25, p
Revise to read: p. Do not mix- match CBRN and non-CBRN parts on a CBRN APR for CBRN response.

Page 26 (2)
Comment: This section introduces the term "unmask", or "unmasking" which are not terms used by civilians. The term "doffing" is also used in other places. NIOSH should standardize on a term, preferably "doff" or "doffing".

Page 26 e
Comment: The term "buddy system" appears in standards and is generally recognized by health and safety professionals as well as the fire service.
Revise to read: e. Use the ~~two-man concept~~ buddy system to ensure each responder is properly protected.

Page 26 f
Comment: The language should be rewritten for clarity. As worded, the example tells the reader to use "All Clear" when an incident has been detected.
Revise to read: f. Use common commands that tell all concerned when to don APR**s** in an attempt to preclude exposure. Use common all clear commands to tell all responders when it is safe to un-mask. Use all communication**s** means available to conduct this warning program. Such examples might be verbal "GAS, GAS, GAS" with corresponding hand movements to tell responders a CBRN incident has been detected or to indicate when the respirator should be donned, and ~~when~~ once donned and "All Clear", "All Clear" voice command or other equivalent techniques to tell responders a CBRN incident ~~has been detected or expected~~ is over or it is okay to remove the respirator.

Page 28, (2)
Comment: This paragraph should be renumbered (3).

Page 28, h
Comment: The terms "liquid control line" and "vapor control line" should be defined because most of the readers will probably not know what these terms mean.

Page 28, j
Comment: The discussion on decontamination needs to separate CWAs from the other materials.

Page 29, 7b Software first line
Revise to read: " ~~Data~~ Software programs available on the OSHA website …"

Page 29 7b
Comment: In the third paragraph, the last sentence should be modified and would be a better fit at the end on the second paragraph.
Revise to read: The respirator manufacturer may have a software program on their website which includes their specific CBRN canister and CWA. Users should contact the manufacturer for questions about using a manufacturer's software program. The OSHA software and some manufacturer's software also allows for chemical data (such as molecular weight and vapor pressure) to be entered if the specific chemical is not listed in the software's database.

Page 29, 7b, last paragraph
Comment: It is not clear as to why only the NIOSH TRAs can be used as surrogates. A good chemist should be able to choose a surrogate that may give a better prediction of service life than the TRA. For example, there are much better surrogates for GB than cyclohexane when it comes to estimating canister life. In addition the last sentence is not correct. A person could enter the concentration (in ppm) of the acid gas anticipated or measured and calculate the life for each of the five TRAs and use the most conservative estimate. This sentence should be deleted.

Page 30, 7c Manufacturer's Test Data
Comment: It appears that NIOSH is telling the user that the canister cannot be used any longer than the CAP level; for example, a CAP 1 canister could only be used for 15 minutes. This is inconsistent with establishing a canister change schedule. This document, in our opinion never clearly states that the canister will be disposed based on the shorter time of either the CRUL when the entire respirator is discarded or when the time for canister change out is reached.
Revise to read: For those agents which are chemical warfare agents, the canister service life is limited by the CBRN respirator use life (CRUL) limitations stated in caution and limitation 'UU' ~~apply and canister service life is limited to the rated CBRN Cap level supporting~~ or the time established by the change schedule, whichever is shorter. The CRUL for a CBRN APR system service life is a maximum of 8 continuous hours for a CWA gas or vapor or 2 hours for a CWA liquid and the canister is disposed along with the rest of the respirator system. If the canister service life as indicated by the change schedule is less than CRUL for either the liquid exposure or vapor exposure, the canister would be changed at the earlier time.

Page 30, 7d, Rules of Thumb
Comment: As a minimum, we recommend that NIOSH cite the most recent edition of publications. Rules of thumb should be used in conjunction with the manufacturer's data only; not as a stand-alone. The discussion on cartridges is not appropriate since these are canisters.
Revise to read: The *Rules of Thumb* may provide a rough estimation of canister service life, but only for single organic vapors (AIHA 2003). They should **NOT** be used as the sole method

of determining service life. Entering into the *rules of thumb* with a chemical warfare agent can produce varying results. ~~These rules state that industrial organic vapor cartridges will last eight hours if the organic vapor has a boiling point of greater than 70°C, the vapor's concentration is less than 200 ppm, and the worker has a breathing rate of 30 liters per minute (moderate work).~~ These rules state that service life is directly proportional to the amount of carbon. Therefore cartridge service life for a cartridge can be increased proportionally for a canister.

Page 32, 8. Developing NIOSH CBRN Respirator Guidance
This section should be renumbered 9.

Page 32, definition Assigned Protection Factor
Comment: This definition should be very clear that this is the NIOSH recommended APF.
Revise to read: An APF of 50 is assigned by NIOSH to the CBRN APR.

Page 32, definition Biological Agents
Revise to read: Biological Agents – Biological agents consist of micro-organisms such as pathogens (which include disease-causing bacteria and viruses) and those toxins produced by microorganisms.

Page 32-33, definition Chemical Warfare Agents
Comment: As written, this definition includes additional chemicals that may degrade the respirator materials, but the user has no way of knowing what those chemicals are. Hence, the definition is impractical.
Revised with comment: "…~~chemicals that exhibit degrading or destructive effects on respirator materials, and other chemicals for which decontamination procedures are unable to decontaminate the respirator to a safe level for reuse~~."

Page 33, definition Maximum Use Concentration, last sentence
Revise to read: An OEL can be a NIOSH recommended exposure limit (REL), an OSHA permissible exposure limit (PEL), a short term exposure limit, ceiling limit, or peak limit. ~~or any other exposure limit for a hazardous substance~~.

Page 35, definition Test Representative Agent
Revise to read: Refers to any of the 11 chemicals (10 gases and vapors and 1 particulate ~~aerosol~~) NIOSH uses for certification testing of the CBRN APR canister.

Page 39. Organic vapor table
Comment: This says the CWAs are in the organic vapor family, but this is not correct. The blood agents, which are CWAs, are not in the OV family.

Thank you for your consideration.

Sincerely,

Daniel K. Shipp
President